

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THOMAS BEDNAR,

Plaintiff,

-against-

CLEVELAND BIOLABS, INC., LEA
VERNY, RANDY S. SALUCK,
ALEXANDER ANDRYUSHECHKIN,
DANIIL TALYANSKIY, ANNA
EVDOKIMOVA, IVAN FEDYUNIN,

Defendants.

Case No.: _____

COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiff, Thomas Bednar (“Plaintiff”), by his undersigned attorneys, alleges upon personal knowledge with respect to himself, and information and belief based upon, *inter alia*, the investigation of counsel as to all other allegations herein, as follows:

NATURE OF THE ACTION

1. This is an action brought by Plaintiff against Cleveland BioLabs, Inc. (“CBLI” or the “Company”) and the members of the Company’s board of directors (collectively referred to as the “Board” or the “Individual Defendants” and, together with CBLI, the “Defendants”) for their violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 (“Exchange Act”), 15 U.S.C. §§ 78n(a) and 78t(a), and SEC Rule 14a-9, 17 C.F.R. § 240.14a-9, in connection with the proposed merger (the “Proposed Merger”) between CBLI and Cytocom, Inc. (“Cytocom”). Plaintiff also asserts a claim against the Individual Defendants for breaching their fiduciary duty of candor/disclosure under state law.

2. On October 16, 2020, CBLI entered into an Agreement and Plan of Merger (the “Merger Agreement”), pursuant to which High Street Acquisition Corp., a direct, wholly owned

subsidiary of CBLI, will merge with and into Cytocom, with Cytocom surviving as a wholly owned subsidiary of CBLI. While the Proposed Merger will technically result in the acquisition of Cytocom by CBLI, in reality it is a takeover of CBLI by Cytocom. That is because immediately after the Proposed Merger, CBLI securityholders as of immediately prior to the Proposed Merger are expected to own approximately 39% of the outstanding shares of the combined company on a fully diluted basis and former Cytocom securityholders are expected to own approximately 61% of the outstanding shares of the combined company on a fully diluted basis.¹ What is more, after consummation of the Proposed Merger, CBLI will be renamed “Cytocom, Inc.” and the parties expect that the common stock of the combined company will trade on Nasdaq under the symbol “CYTO.”

3. On February 12, 2021, in order to convince CBLI shareholders to vote in favor of the Proposed Merger, Defendants authorized the filing of a materially incomplete and misleading preliminary proxy statement/prospectus on Form S-4 (the “Proxy”) with the Securities and Exchange Commission (“SEC”), in violation of Sections 14(a) and 20(a) of the Exchange Act and in breach of the Individual Defendants’ duty of candor/disclosure. In particular, the Proxy contains materially incomplete and misleading information concerning: (i) financial projections for the Company and Cytocom; (ii) the valuation analyses performed by CBLI’s financial advisor, Cassel Salpeter & Co., LLC (“Cassel Salpeter”), in support of its fairness opinion; (iii) the process that culminated in the Proposed Merger; and (iv) the scientific assets of Cytocom that CBLI shareholders are “acquiring” in the Proposed Merger.

¹ This estimate is subject to adjustment prior to closing of the Proposed Merger based on the outstanding number of shares of Cytocom and CBLI and the respective net cash balances of Cytocom and CBLI and, as a result, CBLI securityholders could own more, and former Cytocom securityholders could own less, or vice versa, of the fully diluted common stock of the combined company, following the closing of the Proposed Merger.

4. The special meeting of CBLI shareholders to vote on the Proposed Merger (the “Shareholder Vote”) will soon be scheduled, and the Proposed Merger is expected to close in the second quarter of 2021. It is imperative that the material information that has been omitted from the Proxy is disclosed prior to the Shareholder Vote so Plaintiff can cast an informed vote and properly exercise his corporate suffrage rights.

5. For these reasons, and as set forth in detail herein, Plaintiff asserts claims against Defendants for violations of Sections 14(a) and 20(a) of the Exchange Act and breach of the duty of candor/disclosure. Plaintiff seeks to enjoin Defendants from taking any steps to consummate the Proposed Merger until the material information discussed herein is disclosed to CBLI’s shareholders sufficiently in advance of the Shareholder Vote or, in the event the Proposed Merger is consummated, to recover damages resulting from the Defendants’ violations of the Exchange Act and breach of the duty of candor/disclosure.

JURISDICTION AND VENUE

7. This Court has original jurisdiction over this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331 (federal question jurisdiction) as Plaintiff alleges violations of Sections 14(a) and 20(a) of the Exchange Act.

8. The Court has supplemental jurisdiction over the state law claim for breach of the duty of candor/disclosure pursuant to 28 U.S.C. § 1367.

9. Personal jurisdiction exists over each Defendant either because the Defendant conducts business in or maintains operations in this District or is an individual who is either present in this District for jurisdictional purposes or has sufficient minimum contacts with this District as to render the exercise of jurisdiction over the Defendants by this Court permissible under traditional notions of fair play and substantial justice. “Where a federal statute such as Section 27

of the [Exchange] Act confers nationwide service of process, the question becomes whether the party has sufficient contacts with the United States, not any particular state.” *Sec. Inv’r Prot. Corp. v. Vigman* 764 F.2d 1309, 1315 (9th Cir. 1985). “[S]o long as a defendant has minimum contacts with the United States, Section 27 of the Act confers personal jurisdiction over the defendant in any federal district court.” *Id.* at 1316.

10. Venue is proper in this District under Section 27 of the Exchange Act and 28 U.S.C. § 1391, because Defendants are found or are inhabitants or transact business in this District. Indeed, CBLI common stock trades on the Nasdaq Capital Market, which is headquartered in this District rendering venue in this District appropriate. *See, e.g., United States v. Svoboda*, 347 F.3d 471, 484 n.13 (2d Cir. 2003) (collecting cases).

PARTIES

11. Plaintiff is, and at all relevant times has been, a holder of CBLI common stock.

12. Defendant CBLI is a biopharmaceutical company incorporated in Delaware with its principal place of business located in Buffalo, New York. The Company’s common stock is listed on the Nasdaq Capital Market under the symbol “CBLI.”

13. Individual Defendant Lea Verny is, and has been at all relevant times, the Chairman of the Board of the Company.

14. Individual Defendant Randy S. Saluck is, and has been at all relevant times, a director of the Company.

15. Individual Defendant Alexander Andryushechkin is, and has been at all relevant times, a director of the Company.

16. Individual Defendant, Daniil Talyanskiy is, and has been at all relevant times, a director of the Company.

17. Individual Defendant Anna Evdokimova is, and has been at all relevant times, a director of the Company.

18. Individual Defendant Ivan Fedyunin is, and has been at all relevant times, a director of the Company.

19. The Individual Defendants referred to in ¶¶ 13-18 are collectively referred to herein as the “Individual Defendants” and/or the “Board”, and together with CBLI they are referred to herein as the “Defendants.”

SUBSTANTIVE ALLEGATIONS

I. Relevant Corporate Background

20. CBLI is a biopharmaceutical company that develops novel approaches to activate the immune system and address serious medical needs. Its proprietary platform of Toll-like immune receptor activators has applications in mitigation of radiation injury and immuno-oncology. CBLI was incorporated in Delaware in June 2003 as a corporation spun off from The Cleveland Clinic.

21. On July 9, 2015, CBLI closed a private placement transaction with Mr. David Davidovich, a venture capital investor, pursuant to which the Company issued and sold to him an aggregate of 6,459,948 shares of the Company’s common stock, for an aggregate purchase price of approximately \$25 million, or \$3.87 per share, under the terms of the Securities Purchase Agreement dated June 24, 2015 (the “Purchase Agreement”). Under the Purchase Agreement, Mr. Davidovich had the right to nominate for election to the Board a majority of directors until such time that he no longer held a majority of the issued and outstanding common stock of the Company. As a result of the closing of the issuance and sale of the shares under the terms of the Purchase Agreement, Mr. Davidovich assumed effective control of the Company through his ownership of

approximately 60% of CBLI's outstanding shares of common stock and his right to nominate for election to the Board a majority of CBLI's directors.

22. While, as a result of additional issuances of CBLI's common stock during the fiscal year ending December 31, 2020, Mr. Davidovich no longer holds a majority of the issued and outstanding common stock of the Company, as of October 7, 2020, he still owns approximately 49.63% of the Company's outstanding common stock. What is more, Individual Defendants Ms. Evdokimova and Mr. Fedyunin are each employees of Millhouse LLC, an asset management company of which Mr. Davidovich serves as the Chief Executive Officer, and Individual Defendants Talyanskiy and Andryushechkin were nominated to the Board by Mr. Davidovich.

23. Cytocom is a clinical-stage biopharmaceutical company that purportedly develops novel immunotherapies targeting autoimmune, inflammatory, infectious diseases and cancers based on a proprietary, Advanced Immunomodulating Multi-receptor System platform ("AIMS"), designed to rebalance the body's immune system and restore homeostasis. Through AIMS, Cytocom has purportedly advanced four late-stage developmental product candidates in its CYTO-200 and CYTO-400 AIMS programs evaluating noroxymorphone and proenkephalin analogs, respectively, for the treatment of certain cancer, inflammatory, autoimmune, and infectious diseases: CYTO-201, CYTO-202, CYTO-203 and CYTO-401.

24. However, as noted in the Proxy, Cytocom has not demonstrated the ability to successfully complete a Phase 3 clinical trial, submit a New Drug Application, or NDA, for a product candidate, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on Cytocom's behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization.

II. Background to the Proposed Transaction

25. CBLI's most advanced product candidate is entolimod, which CBLI believes is the most efficacious medical radiation countermeasure currently in development. In 2015, following confirmation from the FDA of the sufficiency of CBLI's existing efficacy and safety data and animal-to-human dose conversion, CBLI submitted to the FDA an application for pre-Emergency Use Authorization ("pre-EUA"), a form of authorization granted by the FDA under certain circumstances. Since 2015, the FDA has indicated that a biocomparability exercise was necessary to compare the entolimod formulation used to perform early studies with the entolimod formulation planned for stock piling under the pre-EUA; this exercise is complete and the FDA agrees that, for pre-EUA purposes, biocomparability has been demonstrated. According to the Proxy, this agreement is not yet in place for a future Biologics License Application ("BLA"), and the FDA has also indicated that additional chemistry and manufacturing work must be performed for pre-EUA and BLA purposes. The FDA review of the pre-clinical and clinical portions of the pre-EUA are ongoing.

26. If the FDA authorizes the pre-EUA application, then Federal agencies will be free to procure entolimod for stockpiling so that the drug is available to distribute in the event of an emergency – *i.e.*, prior to the drug being formally approved by FDA under a BLA. Such authorization is not equivalent to full licensure through approval of a BLA, but precedes full licensure and, importantly, would position entolimod for potential sales in advance of full licensure in the U.S, and pre-EUA status will similarly position CBLI to explore sales opportunities with foreign governments. CBLI is awaiting the results of its pre-EUA application.

27. The Proxy indicates that in early 2019 the Board became concerned with CBLI's future operating plan, especially as it had yet to receive pre-EUA for its principal drug product

candidate, entolimod, and was unsure as to when such approval would be granted, if ever. In May 2019, CBLI began to explore a sale of CBLI's assets that did not pertain to the development and commercialization of entolimod, which then evolved into exploration of a more transformative strategic transaction. According to the Proxy, from June to August 2019, CBLI engaged in discussions with three potential counterparties, but no proposal resulted from these efforts. In September 2019, CBLI received a letter from the NASDAQ indicating that CBLI was no longer compliant with the NASDAQ's continued listing standards and was at risk of having its common stock delisted from the exchange. Then, on November 12, 2019, CBLI's then-CEO resigned effective as of the end of December 13, 2019.

28. In response, on December 3, 2019, CBLI engaged Rock Creek Advisors, LLC ("Rock Creek") to assist the Board in determining how to proceed strategically, in light of CBLI's lack of capital resources, the potential delisting of its common stock from the NASDAQ, and its lack of permanent management. In early January 2020, the Board received the final report of Rock Creek. After analyzing CBLI's business and financial statements, *including certain pro forma financial statements, Rock Creek recommended that CBLI continue its efforts to obtain pre-EUA approval from the FDA and raise new capital to the extent needed to do so.* In other words, Rock Creek recommended a standalone plan. The Board accepted the Rock Creek report and determined not to take any definitive steps at that time towards "going dark" or dissolving CBLI.

29. Later in January 2020, the COVID-19 pandemic began to impact the global economy and the financial markets, causing CBLI's stock to begin trading higher. The Company sought to take advantage of the higher stock prices through a capital raise, but due to its delinquency in filing its annual report the Company was unable to immediately take advantage of the improved market for its stock.

30. On April 16, 2020, Individual Defendant Talyanskiy, a Davidovich nominee to the Board, began discussions with representatives of Cytocom with respect to the possibility of a strategic transaction after being introduced by Dr. Andrei Gudkov, CBLI's Chief Scientific Officer. Talyanskiy had several telephone calls, and exchanged e-mail messages with, these representatives, and, on April 21, 2020, Talyanskiy presented to the Board general information about Cytocom's business and drug product candidates and indicated that he believed that CBLI entering into a transaction with Cytocom could be an interesting opportunity for consideration. Talyanskiy also presented to the Board the terms of a draft memorandum of understanding, or MOU, that had been given to him by representatives of Cytocom earlier that morning.

31. The Board discussed the MOU and determined to continue negotiations with Cytocom with the objective of entering into the MOU on agreeable terms. The Board also created a Special Committee, including Defendant Talyanskiy, a Davidovich nominee, to efficiently consider and negotiate a potential transaction with Cytocom. Notably, it appears that, at the time, Davidovich owned over 56.65% of CBLI's outstanding shares, and was thus the Company's controlling shareholder. The MOU was executed on April 28, 2020, and provided for a 45-day exclusivity period. It is unclear from the Proxy when, or if, the Company agreed to extend this exclusivity period. Notably, it was not until October 10, 2020, over five months following the execution of the MOU, that a final form of the draft Merger Agreement was agreed to by the parties, and it does not appear that the Company conducted any outreach or performed any market check for potential counterparties during that time.

32. Ultimately, on October 19, 2020, CBLI and Cytocom issued a joint press release announcing the Proposed Merger, which states in relevant part:

Cytocom and Cleveland BioLabs Announce Definitive Merger Agreement

Merger to create a single public company focused on the development and commercialization of immunotherapies for oncology, infectious disease, inflammation and auto-immune mediated conditions

WINTER PARK, Fla., and BUFFALO, NY, October 19, 2020 /PRNewswire/ -- Cytocom, Inc. (Cytocom), a leading biopharmaceutical company in the area of immune-modulation, and Cleveland BioLabs, Inc., (NASDAQ: CBLI), an innovative biopharmaceutical company developing novel approaches to activate the immune system, today announced that they have entered into a definitive merger agreement to combine their businesses in an all-stock transaction. Cytocom shareholders will have a majority position in the newly combined entity, which the parties anticipate will continue to be listed on the Nasdaq, and the initial Board of Directors for the combined company will consist of four members selected by Cytocom and three members selected by Cleveland BioLabs. The Boards of Directors of both companies have approved the combination.

Each party to the proposed merger believes that the combined company will create near-term commercial opportunities in numerous areas of significant unmet medical needs including acute radiation injury, oncology, infectious disease, inflammation and autoimmune-mediated conditions, with multiple commercial, regulatory and clinical milestones expected over the next 12 to 18 months. Operating as “Cytocom, Inc.” and under the leadership of Cytocom's experienced management team, the combined company will be positioned for consistent growth.

Overview

Michael K. Handley, President and Chief Executive Officer of Cytocom, stated, “Our merger with Cleveland BioLabs and its subsequent immune-focused platform will be a transformative growth opportunity for Cytocom and Cleveland BioLabs shareholders. We believe that the combination of these highly complementary late-stage pipelines will strengthen our position and advance our efforts to unlock the potential of immune-modulating agents in the treatment of serious medical conditions. Further, this merger will enhance our ability to become a recognized leader in immune-modulating treatments and builds on the momentum created by our recent acquisition of ImQuest Life Sciences. We plan to utilize the combined platform to further drive value with additional clinical and commercial products and continue to seek strategic partnerships and acquisitions.”

Dr. Andrei Gudkov, Chief Scientific Officer of Cleveland BioLabs, said: “This is an exciting day for Cleveland BioLabs and a great opportunity for our stockholders. The merger with Cytocom will allow us to add the strength of our science and bright perspectives associated with Entolimod development in cancer treatment and radiation defense arenas with a string of immunomodulators developed by Cytocom to form a powerful blend of conceptually and scientifically aligned products. We believe that the merger with Cytocom is the ideal way to unlock the value of our

technology platform and our lead drug candidate, Entolimod, and I look forward to seeing this exciting new therapy advance through the clinic.”

33. According to a Form 8-K filed with the SEC by the Company on February 19, 2021, Cytocom expects to report that, as of December 31, 2020, it has approximately \$0.6 million in cash, cash equivalents, and short-term investments, which together with cash raised in the first two months of 2021 are expected to fund its projected operating requirements and allow it to fund its operating plan, in each case, into May 2021. Thus, it appears that Cytocom plans to raise an additional \$50 million to capitalize the merged entity via a PIPE or follow-on share offering.²

III. The Proxy Omits Material Information

34. On February 12, 2021, Defendants filed the materially incomplete and misleading Proxy with the SEC. The Individual Defendants were obligated to carefully review the Proxy before it was filed with the SEC and disseminated to the Company’s shareholders to ensure that it did not contain any material misrepresentations or omissions. However, the Proxy misrepresents and/or omits material information that is necessary for the Company’s shareholders to make an informed decision in connection with the Proposed Merger.

A. The Proxy Omits CBLI’s and Cytocom’s Financial Projections

35. First, the Proxy omits critical information relating to the Company’s financial projections. As discussed above, in 2019, the Board became concerned with CBLI’s future operating plan and engaged Rock Creek to assist in determining how to proceed strategically. In early January 2020, after analyzing CBLI’s business and financial statements, *including certain pro forma financial statements*, Rock Creek recommended that CBLI continue its efforts to obtain

² See Dane Hamilton, *Cytocom looking to raise USD 50m to fund advanced clinical trials, CEO says*, available at: <https://www.mergermarket.com/info/cytocom-looking-raise-usd-50m-fund-advanced-clinical-trials-ceo-says> (last visited March 8, 2021) (“Cytocom has already started raising USD 25m from strategics and institutional investors and expects to close that round by the time the merger with [CBLI] closes . . . After that, . . . the company plans to raise ‘at least another USD 25m’ through a PIPE or follow-on share offering to further capitalize the merged entity.”).

pre-EUA approval from the FDA and raise new capital to the extent needed to do so. The Board accepted the Rock Creek report to remain a standalone company and determined not to take any definitive steps at that time towards “going dark” or dissolving CBLI.

36. Nonetheless, the Proxy fails to disclose *any* financial projections or forecasts for CBLI and/or entolimod. To the extent that the Company’s management prepared projections for the Company, those projections, including but not limited to the Company’s cash burn, must be disclosed for CBLI’s shareholders to value their shares and the consideration to be received as a result of the Proposed Merger.

37. Second, the Proxy indicates that, in connection with its fairness opinion, Cassel Salpeter reviewed and relied upon “financial projections with respect to the future financial performance of Cytocom on a standalone basis” prepared by Cytocom’s management (the “Projections”). Cassel Salpeter also “performed a risk-adjusted net present value analysis of Cytocom by calculating the estimated net present value of the risk-adjusted free cash flows of Cytocom based on the Projections.” However, again the Proxy wholly omits the Projections, including, but not limited to, Cytocom’s free cash flows used in Cassel Salpeter’s analyses.

38. The omission of the Projections and any projections related to CBLI renders the Proxy materially incomplete and provides a misleading valuation picture of CBLI and the value of the portion of the combined company to be received by CBLI’s shareholders. Simply put, complete and accurate financial projections are irreplaceable when it comes to fully and fairly understanding the value of a merger transaction as they speak directly to question put before shareholders: is a reduced stake in the combined company worth more or less than a maintaining full ownership of CBLI as a standalone.

B. The Misleadingly Incomplete Summary of Cassel Salpeter's Analyses

39. The Proxy describes Cassel Salpeter's fairness opinion and the various valuation analyses performed in support of that opinion. Defendants concede the materiality of this information in citing Cassel Salpeter's fairness opinion and their valuation analyses among the factors the Board considered in making its recommendation to CBLI's shareholders. However, the summary of Cassel Salpeter's fairness opinion and analyses provided in the Proxy fails to include key inputs and assumptions underlying the analyses. Without this information, as described below, CBLI's shareholders are unable to fully understand these analyses and, thus, are unable to determine what weight, if any, to place on Cassel Salpeter's fairness opinion in determining how to vote on the Proposed Merger. *See* Proxy at 124 ("Cassel Salpeter believes that the analyses underlying the opinion must be considered as a whole and that selecting portions of its analyses or the factors it considered, without considering all analyses and factors underlying the opinion collectively, could create a misleading or incomplete view of the analyses performed by Cassel Salpeter in preparing the opinion."). This omitted information, if disclosed, would significantly alter the total mix of information available to CBLI shareholders.

40. For example, and third, in summarizing Cassel Salpeter's *Financial Analysis of Cytocom*, the Proxy fails to disclose the following key information used in the analyses: (i) the projected free cash flows used in the analysis (as described above); (ii) the inputs and assumptions underlying the discount rate ranges used in the analysis; and (iii) the inputs and assumptions underlying the terminal growth rate range used in the analysis.

41. These key inputs are material to CBLI shareholders, and their omission renders the summary of the analysis incomplete and misleading. As a highly-respected professor explained in one of the most thorough law review articles regarding the fundamental flaws with the valuation

analyses bankers perform in support of fairness opinions, in a discounted cash flow analysis a banker takes management's forecasts, and then makes several key choices "each of which can significantly affect the final valuation." Steven M. Davidoff, *Fairness Opinions*, 55 Am. U.L. Rev. 1557, 1576 (2006). Such choices include "the appropriate discount rate, and the terminal value..."

Id. As Professor Davidoff explains:

There is substantial leeway to determine each of these, and any change can markedly affect the discounted cash flow value. For example, a change in the discount rate by one percent on a stream of cash flows in the billions of dollars can change the discounted cash flow value by tens if not hundreds of millions of dollars.... This issue arises not only with a discounted cash flow analysis, but with each of the other valuation techniques. This dazzling variability makes it difficult to rely, compare, or analyze the valuations underlying a fairness opinion unless full disclosure is made of the various inputs in the valuation process, the weight assigned for each, and the rationale underlying these choices. The substantial discretion and lack of guidelines and standards also makes the process vulnerable to manipulation to arrive at the "right" answer for fairness. This raises a further dilemma in light of the conflicted nature of the investment banks who often provide these opinions.

Id. at 1577-78. Without the above-omitted information, especially the free cash flows, CBLI's shareholders are misled as to the reasonableness or reliability of Cassel Salpeter's analyses, and unable to properly assess the fairness of the Proposed Merger.

42. Fourth, in summarizing Cassel Salpeter's *Selected Companies Analysis*, the Proxy fails to disclose: (i) the individual metrics and/or multiples observed for each company used in the analysis; (2) Cassel Salpeter's full basis and rationale for selecting the companies; and (3) the inputs and assumptions underlying Cassel Salpeter's calculation of the implied aggregate equity value reference range for Cytocom. Without this information, shareholders are unable to assess whether the allegedly comparable companies chosen are truly comparable or if they were chosen to present the Proposed Merger in the most favorable light.

43. Fifth, the Proxy indicates that "[f]or purposes of its analyses and opinion, Cassel

Salpeter at the [CBLI's] special committee's direction assumed that the number of shares of [CBLI] Common Stock comprising the merger consideration would be equal to approximately 57.8% of the shares of combined company's common stock outstanding immediately after the merger." Notably, in its discussion of the merger consideration and exchange ratio formula, the Proxy indicates that "the valuation of [CBLI] was assumed to be \$39 million and the valuation of Cytocom was assumed to be \$61 million," subject to certain adjustments based on the amount of each company's net cash at closing, and, that "if there is no adjustment to the respective valuations of each of the companies, then the former Cytocom securityholders will own, or hold rights to acquire, approximately 61% of the common stock of the combined company, on a fully diluted basis." In light of this fact, it is unclear from the Proxy why the special committee directed Cassel Salpeter to assume that the number of shares of CBLI Common Stock comprising the merger consideration would be equal to approximately 57.8% of the shares of combined company's common stock outstanding immediately after the Proposed Merger.

44. Moreover, while the Proxy does note that Cassel Salpeter's analyses and opinion do not account for the effect of Cytocom's stock-based acquisition of ImQuest Life Sciences, Inc., which "complicated negotiation of the exchange ratio," it is unclear whether the exchange ratio and/or merger consideration give effect to the following events that were *undisclosed* in the Proxy: (1) the February 19, 2021 Securities Purchase Agreement CBLI entered into with several healthcare-focused and institutional investors for the sale by the Company of 2,000,000 shares of the Company's common stock in a registered direct offering (the "Purchase Agreement"), and/or (2) Cytocom's plan to raise \$50 million to capitalize the merged entity through a PIPE transaction or follow-on share offering. Accordingly, CBLI shareholders must be provided with additional information regarding the basis and rationale underlying the special committee's selection of

57.8% for the merger consideration, and the effect that the Purchase Agreement and Cytocom's planned capitalization efforts will have on the ownership percentages of the combined company after completion of the Proposed Merger.

C. Process Related Disclosures

45. Sixth, as discussed above, the Company engaged in discussions regarding potential strategic transactions with at least three companies in 2019, including the performance of due diligence. However, the Proxy fails to disclose whether the Company entered into any confidentiality and/or non-disclosure agreements with those companies and/or in connection with its review of any potential strategic transaction, and if so, the terms of those agreements, including whether the agreements contained standstill and/or "don't ask, don't waive" provisions and whether those provisions are still in effect or have fallen away.

46. The failure to plainly disclose the existence of DADW provisions and confidentiality agreements creates the false impression that a prior bidder can now make a superior proposal. If there are confidentiality agreements containing DADW provisions, then those parties could only make a superior proposal by breaching the agreement—since in order to make the superior proposal, they would have to ask for a waiver, either directly or indirectly. Any reasonable shareholder would deem the fact that the most likely potential topping bidders in the marketplace may be precluded.

47. Seventh, according to the Proxy, immediately following the Proposed Merger, the combined company's board of directors will be composed of up to seven members, consisting of (i) three individuals designated by CBLI, two of whom will be Individual Defendants Randy Saluck and Lea Verny and the third of whom will be designated before the closing of the merger, and (ii) four individuals designated by Cytocom. However, the Proxy fails to disclose *any*

information regarding the timing and substance of these negotiations. Communications regarding post-transaction employment during the negotiation of the underlying transaction must be disclosed to stockholders. This information is necessary for stockholders to understand potential conflicts of interest of management and the Board, as that information provides illumination concerning motivations that would prevent fiduciaries from acting solely in the best interests of the Company's stockholders.

48. Eighth, the Proxy indicates that Cassel Salpeter received a fee of *just* \$75,000 for rendering its fairness opinion, no portion of which was contingent upon the consummation of the Proposed Merger. It is unclear from the Proxy whether Cassel Salpeter received any additional fees from the Company for serving as financial advisor during the negotiations that culminated in the Proposed Merger. Relatedly, the Proxy fails to disclose any information regarding the potential conflicts of interest faced by Cassel Salpeter, including whether Cassel Salpeter has previously performed services for and/or received fees or compensation from CBLI and/or Cytocom (or their respective affiliates). Indeed, the Proxy indicates that “[t]he Special Committee selected Cassel Salpeter to act as [CBLI’s] financial advisor based on . . . its knowledge of and involvement in recent transactions in the biopharmaceutical industry, *and its familiarity with [CBLI] and its business.*” Full disclosure of a financial advisor’s compensation and all potential conflicts is material information stockholders are entitled to receive in deciding what weight to place on the opinions and roles played by the advisor in the Proposed Merger.

D. Disclosures Regarding Cytocom’s Assets

49. Finally, the Proxy provides a woefully inadequate description of Cytocom’s AIMS Platforms, product candidates, and scientific assets, which CBLI shareholders are “acquiring” in the Proposed Merger.

50. The Proxy states that

Cytocom is a clinical-stage biopharmaceutical company developing novel immunotherapies targeting autoimmune, inflammatory and infectious diseases and cancers based on a proprietary, multi receptor platform, or the AIMS platform, designed to rebalance the body's immune system and restore homeostasis. Cytocom believes that its technologies developed through its CYTO-200 and CYTO-400 AIMS programs can meaningfully leverage the human immune system for prophylactic and therapeutic purposes by eliciting killer T cell response levels not achieved by other published immunotherapy approaches. Cytocom is developing therapies designed to elicit a robust and durable response of antigen-specific killer T cells and antibodies to activate essential immune defenses against autoimmune, inflammatory and, infectious diseases and cancers. Cytocom believes its immunomodulatory technology has the potential to restore balance between the cellular (Th1) and the humoral (Th2) immune systems, with the goal to establish immunotherapies that improve outcomes for patients suffering with autoimmune, inflammatory and infectious diseases and cancers.

51. The Proxy further provides that the "CYTO-200 AIMS program centers around developing noroxymorphone analogs that modulate numerous receptors associated with autoimmune, inflammatory, and infectious diseases and cancers" and the "CYTO-400 AIMS program utilizes an injectable opioid growth factor peptide platform that exerts profound inhibition on the proliferation of cancer cells *in vitro* and *in vivo*." One of Cytocom's lead product candidates, CYTO-201, "is a noroxymorphone-n-substituted-methyl cyclopropyl analog intended to target the remission of moderate to severe Crohn's disease."

52. It appears that CYTO-201 is basically low-dose Naltrexone, an inexpensive, readily available, generic medication routinely used in the treatment of opioid and alcohol addiction. Indeed, in evaluating the efficacy of CYTO-201, CYTO-202, and CYTO-203, Cytocom relies heavily on published data and clinical trials which tested *low-dose naltrexone therapy* ("LDN"), thus suggesting that CYTO-201, and the CYTO-200 AIMS program, are off-label uses of LDN for Crohns disease, fibromyalgia, and multiple sclerosis.

53. For example, the Proxy indicates that CYTO-201, CYTO-202, and CYTO-203

have satisfied a Phase 2 clinical trial. But it is unclear whether each product candidate has *individually and independently* satisfied a Phase 2 clinical trial or whether Cytocom is instead promoting the efficacy and potential of its products (CYTO-201, CYTO-202, and CYTO-203) based on clinical trials and/or data *related to LDN*, a readily available generic medication. Specifically, the Proxy states:

In a Phase 2 open-label study involving *17 patients* with histologically active disease and Crohn's disease activity index, or CDAI, typical scores recorded for patients with active disease are 220–450, *a 4.5 mg daily dose of CYTO-201 over 12 weeks resulted in 89% of the patients deemed responders while 67% of patients achieved disease remission.* In a twelve-week Phase 2, randomized, double-blind, placebo-controlled study followed by open-label *administration of CYTO-201* for a further 12 weeks in adults with moderate to severe, active Crohn's disease demonstrated that *88% of CYTO-201-treated* subjects achieved the primary outcome in CDAI score of below 150 signaling remission as compared *with 40% of placebo-treated subjects* at week 12. In addition, *78% of CYTO-201-treated subjects exhibited an endoscopic response as indicated by a 5-point decline in Crohn's disease endoscopic index of severity score from baseline compared with 28% of placebo-treated subjects.* Overall, there were no significant differences in incidence of side effects reported between groups with the exception of fatigue, which was significantly increased in the placebo group. In a second Phase 1/2, randomized, double-blind, placebo-controlled study in pediatric subjects with moderate-to-severe, active Crohn's disease, *CYTO-201 was well-tolerated* with no reported adverse effects and no laboratory abnormalities, 25% of *CYTO-201-treated* subjects were considered in remission (score < 10) and 67% had improved disease activity as determined by a decrease in pediatric CDAI by > 10 points at study end.

(emphasis added). These results are identical to those of clinical studies involving LDN, though

the Proxy misleadingly characterizes those studies as “additional published data,” as follows:

Cytocom believes data from the randomized clinical studies above and additional published data (. . .)³ supports the development of CYTO-201 in phase 3 trials,

³ The following internal citations were omitted, and have been included here with parenthetical information added:

Smith et al., Low-dose naltrexone therapy improves active Crohn's disease. Am J Gastroenterol. 2007 Apr;102(4):820-8

(ClinicalTrials.gov Identifier: NCT00663117; study involved 17 patients enrolled in a study using 4.5 mg *naltrexone* for a twelve week period; reported 89% percent of patients exhibited a response to therapy and 67% achieved a remission; conclusion that “LDN therapy appears effective and safe in subjects with active Crohn's disease.”);

which Cytocom intends to pursue in the first half of 2021, in patients who have failed to respond to or cannot take biologics.

(emphasis added).

54. The Proxy likewise cites to published data and clinical trials involving the administration of LDN when describing its CYTO-202 and CYTO-203 product candidates. However, and again, it is unclear whether Cytocom's CYTO-201, CYTO-202, CYTO-203 product candidates have, themselves, each *individually and independently* satisfied a Phase 2 clinical trial or whether Cytocom is instead extrapolating and relying upon clinical data relating to LDN to demonstrate the *potential* of its CYTO-200 AIMS program and product candidates.

55. Thus, and ninth, in light of the fact that Cytocom's product candidates appear to be off-label uses of a readily available generic drug, the efficacy of which remains uncertain,⁴ Cytocom must provide additional information regarding its CYTO-200 AIMS platform, including:

(a) how Cytocom intends to distinguish its CYTO-200 AIMS platform from other

Smith et al., Therapy with the opioid antagonist naltrexone promotes mucosal healing in active Crohn's disease: a randomized placebo-controlled trial. *Dig Dis Sci.* 2011 Jul;56(7):2088-97

(ClinicalTrials.gov Identifier: NCT00663117; study involved 40 patients enrolled in a study using 4.5 mg *naltrexone* for a twelve week period; reported 88% percent of patients had at least a 70-point decline in CDAI scores compared to 40% of placebo-treated patients, and 78% of subjects treated with naltrexone exhibited an endoscopic response as indicated by a 5-point decline in the Crohn's disease endoscopy index severity score (CDEIS) from baseline compared to 28% response in placebo-treated controls);

Smith et al., Safety and tolerability of low-dose naltrexone therapy in children with moderate to severe Crohn's disease: a pilot study. *J Clin Gastroenterol.* 2013 Apr;47(4):339-45)

(ClinicalTrials.gov Identifier: NCT00715117; study involved 14 children enrolled in pilot study, reported 25% of those treated with *naltrexone* were considered in remission (score ≤ 10) and 67% had improved with mild disease activity).

⁴ See i.e. Patten DK, et al., *The Safety and Efficacy of Low-Dose Naltrexone in the Management of Chronic Pain and Inflammation in Multiple Sclerosis, Fibromyalgia, Crohn's Disease, and Other Chronic Pain Disorders*, Pharmacotherapy. 2018 Mar;38(3):382-389. ("Currently, evidence supports the safety and tolerability of low-dose naltrexone in multiple sclerosis, fibromyalgia, and Crohn's disease. Fewer studies support the efficacy of low-dose naltrexone, with most of these focusing on subjective measures such as quality of life or self-reported pain. These studies do demonstrate that low-dose naltrexone has subjective benefits over placebo, but evidence for more objective measures is limited. However, further randomized controlled trials are needed to determine the efficacy of low-dose naltrexone due to insufficient evidence supporting its use in these disease states.")

LDN therapies and market its product candidates into viable marketable therapeutics;

- (b) all Phase 2 clinical data for studies specifically involving Cytocom's CYTO-201, CYTO-202, and CYTO-203 product candidates, including but not limited to each National Clinical Trial number ("NCT Number"), or similar unique identification, assigned to each study when it was registered;
- (c) chemical equivalency and/or biocompatibility approval from the FDA (if applicable);
- (d) any study or data that indicates that Cytocom's product candidates/noroxymorphone analogs are more therapeutically effective than LDN or have distinct advantages over LDN (or other therapeutic) for Crohns disease, fibromyalgia, and multiple sclerosis; and
- (e) clarifying whether Cytocom's CYTO-201, CYTO-202, and CYTO-203 product candidates are *each* poised for Phase 3 clinical trials, or whether the chart describing Cytocom's product pipeline on page 192 of the Proxy is based on the application of the same product candidate/agent and/or data relating to LDN.

56. In light of the fact that Cytocom's assets and business will form the future of CBLI, CBLI shareholders are entitled to know what they are buying.

* * *

57. In sum, the omission of the above-referenced information renders the Proxy materially incomplete and misleading, in contravention of the Exchange Act and the Individual Defendants' duty of candor/disclosure. Absent disclosure of the foregoing material information

prior to the forthcoming Shareholder Vote, Plaintiff will be unable to cast an informed vote regarding the Proposed Merger, and is thus threatened with irreparable harm, warranting the injunctive relief sought herein.

COUNT I

Against All Defendants for Violations of Section 14(a) of the Exchange Act

58. Plaintiff incorporates each and every allegation set forth above as if fully set forth herein.

59. Section 14(a)(1) of the Exchange Act makes it “unlawful for any person, by the use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 78l of this title.” 15 U.S.C. § 78n(a)(1).

60. Rule 14a-9, promulgated by the SEC pursuant to Section 14(a) of the Exchange Act, provides that proxy communications shall not contain “any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.” 17 C.F.R. § 240.14a-9.

61. The omission of information from a proxy will violate Section 14(a) if other SEC regulations specifically require disclosure of the omitted information.

62. Defendants have issued the Proxy with the intention of soliciting the Company’s common shareholders’ support for the Proposed Merger. Each of the Individual Defendants

reviewed and authorized the dissemination of the Proxy, which fails to provide critical information regarding, amongst other things: (i) financial projections; (ii) Cassel Salpeter's valuation analyses; and (iii) the process that culminated in the Proposed Merger.

63. In so doing, Defendants made misleading statements of fact and/or omitted material facts necessary to make the statements made not misleading. Each of the Individual Defendants, by virtue of their roles as officers and/or directors, were aware of the omitted information but failed to disclose such information, in violation of Section 14(a). The Individual Defendants were therefore negligent, as they had reasonable grounds to believe material facts existed that were misstated or omitted from the Proxy, but nonetheless failed to obtain and disclose such information to the Company's shareholders although they could have done so without extraordinary effort.

64. The Individual Defendants knew or were negligent in not knowing that the Proxy is materially misleading and omits material facts necessary to render it not misleading. The Individual Defendants undoubtedly reviewed and relied upon most if not all of the omitted information identified above in connection with their decision to approve and recommend the Proposed Merger; indeed, the Proxy states that Cassel Salpeter reviewed and discussed their financial analyses with the Board, and further states that the Board considered the financial analyses provided by Cassel Salpeter, as well as their fairness opinion and the assumptions made and matters considered in connection therewith. Further, the Individual Defendants were privy to and had knowledge of the financial projections and the details surrounding the process leading up to the signing of the Merger Agreement. The Individual Defendants knew or were negligent in not knowing that the material information identified above has been omitted from the Proxy, rendering the sections of the Proxy identified above to be materially incomplete and misleading. Indeed, the Individual Defendants were required to, separately, review Cassel Salpeter's analyses in

connection with their receipt of the fairness opinion, question Cassel Salpeter as to their derivation of fairness, and be particularly attentive to the procedures followed in preparing the Proxy and review it carefully before it was disseminated, to corroborate that there are no material misstatements or omissions.

65. The Individual Defendants were, at the very least, negligent in preparing and reviewing the Proxy. The preparation of a proxy statement by corporate insiders containing materially false or misleading statements or omitting a material fact constitutes negligence. The Individual Defendants were negligent in choosing to omit material information from the Proxy or failing to notice the material omissions in the Proxy upon reviewing it, which they were required to do carefully as the Company's directors. Indeed, the Individual Defendants were intricately involved in the process leading up to the signing of the Merger Agreement and preparation and review of the Company's financial projections.

66. CBLI is also deemed negligent as a result of the Individual Defendants' negligence in preparing and reviewing the Proxy.

67. The misrepresentations and omissions in the Proxy are material to Plaintiff, who will be deprived of his right to cast an informed vote on the Proposed Merger if such misrepresentations and omissions are not corrected prior to the special meeting of CBLI shareholders. Plaintiff has no adequate remedy at law. Only through the exercise of this Court's equitable powers can Plaintiff be fully protected from the immediate and irreparable injury that Defendants' actions threaten to inflict.

COUNT II

Against the Individual Defendants for Violations of Section 20(a) of the Exchange Act

68. Plaintiff incorporates each and every allegation set forth above as if fully set forth

herein.

69. The Individual Defendants acted as controlling persons of CBLI within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their positions as officers and/or directors of the Company, and participation in and/or awareness of the Company's operations and/or intimate knowledge of the incomplete and misleading statements contained in the Proxy filed with the SEC, they had the power to influence and control and did influence and control, directly or indirectly, the decision making of the Company, including the content and dissemination of the various statements that Plaintiff contends are materially incomplete and misleading.

70. Each of the Individual Defendants was provided with or had unlimited access to copies of the Proxy and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

71. In particular, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company, and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the Exchange Act violations alleged herein, and exercised the same. The Proxy contains the unanimous recommendation of each of the Individual Defendants to approve the Proposed Merger. They were thus directly involved in preparing this document.

72. In addition, as the Proxy sets forth at length, and as described herein, the Individual Defendants were involved in negotiating, reviewing, and approving the Merger Agreement. The Proxy purports to describe the various issues and information that the Individual Defendants reviewed and considered. The Individual Defendants participated in drafting and/or gave their

input on the content of those descriptions.

73. By virtue of the foregoing, the Individual Defendants have violated Section 20(a) of the Exchange Act.

74. As set forth above, the Individual Defendants had the ability to exercise control over and did control a person or persons who have each violated Section 14(a) and Rule 14a-9 by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, these defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Individual Defendants' conduct, Plaintiff will be irreparably harmed.

75. Plaintiff has no adequate remedy at law. Only through the exercise of this Court's equitable powers can Plaintiff be fully protected from the immediate and irreparable injury that Defendants' actions threaten to inflict.

COUNT III

Against the Individual Defendants for Breach of the Fiduciary Duty of Candor/Disclosure

76. Plaintiff incorporates each and every allegation set forth above as if fully set forth herein.

77. By virtue of their role as directors and/or officers of the Company, the Individual Defendants directly owed Plaintiff and all Company shareholders a fiduciary duty of candor/disclosure, which required them to disclose fully and fairly all material information within their control when they seek shareholder action, and to ensure that the Proxy did not omit any material information or contain any materially misleading statements.

78. As alleged herein, the Individual Defendants breached their duty of candor/disclosure by approving or causing the materially deficient Proxy to be disseminated to Plaintiff and the Company's other public shareholders.

79. The misrepresentations and omissions in the Proxy are material, and Plaintiff will

be deprived of his right to cast an informed vote if such misrepresentations and omissions are not corrected prior to the Shareholder Vote. Where a shareholder has been denied one of the most critical rights he or she possesses—the right to a fully informed vote—the harm suffered is an individual and irreparable harm.

80. Plaintiff has no adequate remedy at law. Only through the exercise of this Court's equitable powers can Plaintiff be fully protected from the immediate and irreparable injury that Defendants' actions threaten to inflict.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment and relief as follows:

A. Preliminarily enjoining Defendants and all persons acting in concert with them from proceeding with the special meeting of CBLI shareholders to vote on the Proposed Merger or consummating the Proposed Merger, until the Company discloses the material information discussed above which has been omitted from the Proxy;

B. Directing the Defendants to account to Plaintiff for all damages sustained as a result of their wrongdoing;

C. Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and expert fees and expenses; and

D. Granting such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: March 24, 2021

OF COUNSEL

KAHN SWICK & FOTI, LLC

Michael Palestina
1100 Poydras Street, Suite 3200
New Orleans, LA 70163
Telephone: 504.455.1400
Direct: 504.648.1843
Facsimile: 504.455-1498
michael.palestina@ksfcounsel.com

MONTEVERDE & ASSOCIATES PC

/s/ Juan E. Monteverde

Juan E. Monteverde (JM-8169)
The Empire State Building
350 Fifth Avenue, Suite 4405
New York, NY 10118
Tel: (212) 971-1341
Fax: (212) 202-7880
Email: jmonteverde@monteverdelaw.com

Attorneys for Plaintiff